REMARKS

Claims 1-14 and 35-41 are pending. Applicants have amended Claims 1-2, 13, and 36-37, support for which may be found in the specification as filed, *inter alia* at page 20, lines 21-22, and have added new claims 42-51. Support for new claims 42, 44, 46, 48 and 50 may found in the specification as filed, *inter alia* at page 17, line 27 to page 18, line 2. Support for new claims 43, 45, 47, 49 and 51 may found in the specification as filed, *inter alia* at page 18, lines 6-8. No new matter has been added by this amendment. Applicants respectfully request reconsideration of the subject application in view of the preceding amendments and for the following reasons.

Rejection under 35 U.S.C. § 103(a)

Claims 1-14 and 35-41 have been rejected under 35 U.S.C. § 103(a) as being obvious over WO 92/13495 to Tripodi ("Tripodi") in view of Miyano et al., U.S. Patent No. 5,116,950 ("Miyano"). Applicants respectfully traverse this rejection and assert that the present claims and remarks below obviate this rejection.

Initially, applicants respectfully note that independent Claims 1, 2, 13, 36 and 37, specify, in part, that the clottable fibrinogen is obtained from precipitating fibrinogen from a sample of non-human mammalian blood plasma with polyethylene glycol 1000 and reprecipitating the fibrinogen with glycine, wherein precipitation of the fibrinogen with polyethylene glycol is performed only **once**, such that at least about 90% of the fibrinogen present in the sample is recovered. (*See,* Specification at page 26). In contrast, Tripodi describes precipitation of fibrinogen with PEG-800 that is conducted **twice**, and therefore, differs from the process to recover fibrinogen, as claimed. As discussed by Applicants in their June 9, 2003 Amendment, the subject specification at page 27, states the precipitation of fibrinogen with PEG 1000, a low molecular weight PEG, leads to a cohesive fibrinogen precipitate that is more readily collected, for resuspension, than fibrinogen precipitate resulting from contact with, for example, PEG 8000, and further, that the use of low molecular weight PEG (such as PEG 1000) facilitates recovery of clottable fibrinogen.

Further, with respect to the Examiner's assertion that the instant claims recite that the "composition contains at least 90% fibrinogen", Applicants respectfully disagree and note that Claims 1 and 13 recite a percentage of fibrinogen "of about 95%, or greater, of total protein present". Moreover, Claims 1, 2, 13, 36 and 37 recite that "at least about 90% of the fibrinogen present in said sample is recovered", indicating that at least 90% of the fibrinogen in the sample of non-human, mammalian blood plasma is recovered, which is **not** equivalent to the percentage of fibrinogen present in the therapeutic composition. (Emphases added)

While Tripodi describes that the fractionation procedure produces a "composition containing at least about 90 to about 98 percent fibrinogen with a low level of conversion to fibrin" (*See,* Tripodi, page 8, lines 25-28), Tripodi does not teach or suggest the therapeutic compositions as claimed. Specifically, Tripodi does not teach a therapeutic composition recovered from a process as recited in Claims 1, 2, 13, 36 and 37, wherein about 95%, or greater, of total protein present in said composition is fibrinogen, of which fibrinogen, **at least about 56% is clottable fibrinogen**. (Emphases added) Moreover, Tripodi does not teach or suggest the claimed therapeutic compositions, wherein "at least about 80% of the fibrinogen is clottable fibrinogen", as recited in new claims 42, 44, 46, 48 and 50, and wherein "about 90% or higher of the fibrinogen is clottable fibrinogen", as recited in new claims 43, 45, 47, 49 and 51. Tripodi does not teach the percent, if any, of clottable fibrinogen or range thereof, present in the described composition.

Tripodi's description of the addition of sufficient diluent to lyophilized fibrinogen to provide a solution containing about 1 to 40 mgs of fibrinogen per ml, does not without more, teach or suggest the *claimed compositions*, e.g. a composition wherein therapeutically effective fibrinogen concentration at a site of treatment is about 10 mg/ml or less (e.g., Claims 1 and 36) or about 30 mg/ml or less (e.g., Claims 2, 13, 37) and wherein the fibrinogen is about 95%, or greater, of total protein present in said composition, of which fibrinogen, at least about 56% is clottable fibrinogen, as recited in the presently pending claims.

Applicants further respectfully assert that Miyano does not cure the shortcomings of Tripodi. Miyano relates to a process for heat treating an aqueous solution containing fibrinogen to thereby inactivate virus(es) therein (*See,* Miyano, Col. 1, lines 5-8). Since fibrinogen is unstable to heat and is thus inactivated during the conventional liquid heating process, Miyano provides a process for heating fibrinogen to inactivate contaminating viruses without inactivating the fibrinogen per se ((*See,* Miyano, Col. 1, lines 31-36). Since Miyano is unrelated to the presently claimed subject matter, one of skill would not be guided to combine its teaching with the primary cited reference, Tripodi, to arrive at the presently claimed invention. Therefore, the combination of the cited references does not render obvious the presently pending claims.

In view of the foregoing, reconsideration and withdrawal of this rejection is respectfully requested.

It is respectfully submitted that the subject application is in condition for allowance. A Notice of Allowance is respectfully requested.

The Examiner is invited to telephone the undersigned attorney at 212-425-7200 if it is believed that a discussion would advance the prosecution of this application.

Respectfully submitted,

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